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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,082	07/08/2003	Stephen Hamilton	GFI-107	9644
210	7590	01/23/2009	EXAMINER	
MERCK AND CO., INC			JOIKE, MICHELE K	
P O BOX 2000			ART UNIT	PAPER NUMBER
RAHWAY, NJ 07065-0907			1636	
			MAIL DATE	DELIVERY MODE
			01/23/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/616,082	HAMILTON, STEPHEN	
	<b>Examiner</b>	<b>Art Unit</b>	
	MICHELE K. JOIKE	1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,10-16,18,19,26-30,57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10-16, 18-19,26-30,57 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/11/08</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 22, 2008 has been entered.

Claims 1, 2, 6, 10-16, 18-19, 26-30, 57 and 58 are pending and examined.

### ***Claim Objections***

Claims 14-19 objected to because of the following informalities: the claims refer to "the mannosidase enzyme". The claims should use the language "the chimeric mannosidase enzyme" to maintain consistency. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6, 10-16, 19, 26-30, 57 and 58 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which applicant regards as the invention. This rejection is maintained for reasons of record.

***Response to Arguments Concerning Claim Rejections – 35 USC § 112 (2)***

Applicant's arguments filed October 22, 2008 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Man $\alpha$  1,3 (Man $\alpha$  1,6) Man $\beta$ 1,4-GlcNA $\beta$ 1,4-GlcNAc-Asn is the description of the oligosaccharide core structure of the product produced by taking GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> (the oligosaccharide substrate) and digesting it with a mannosidase enzyme that is capable of hydrolyzing *in vivo an* oligosaccharide substrate comprising either or both a Man $\alpha$  1,3 and Man $\alpha$  1,6 glycosidic linkage. Mannosidase II is such an enzyme. It can convert the oligosaccharide substrate GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> to the product GlcNAcMan<sub>3</sub>GlcNAc<sub>2</sub>. GlcNAcMan<sub>3</sub>GlcNAc<sub>2</sub> comprises the Man $\alpha$  1,3 (Man $\alpha$  1,6) Man $\beta$ 1,4-GlcNA $\beta$ 1,4-GlcNAc-Asn core structure. Mannosidase IIx and mannosidase III have similar enzymatic activities, but have different substrates.

Applicant's arguments have not been found persuasive for the following reasons.

The preamble does not match the body of the claim, in claims 1 and 2. The preamble has a cell containing an  $\alpha$ -1,2-mannosidase and a GnT I and a product of GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub>. In the body of the claim, GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> is used to make a different product. If GlcNAcMan<sub>3</sub>GlcNAc<sub>2</sub> is the product being made, as argued, then

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why is GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> a product, instead of a substrate. If GlcNAcMan<sub>5</sub>GlcNAc<sub>2</sub> is also being made, there appear to be some missing steps. Although, claims 57 and 58 state that the "desired N-glycan" is GlcNAcMan<sub>3</sub>GlcNAc<sub>2</sub>, the preamble in claims 1 and 2 still cause confusion with the body of the claim.

Claims 1, 2, 6, 10-16, 19, 26-30, 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "desirable N-glycan" in claim claims 1 and 2 is a relative term which renders the claim indefinite. The term "desirable N-glycan" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A "desired N-glycan" produced by the method is claimed, however, it is unclear what properties make the N-glycan desirable. .

Claim 6 recites the limitation "the oligosaccharide substrate" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Allowable Subject Matter***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K Joike/  
Examiner, Art Unit 1636

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